

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|---|----------------------|---|
| DECLARATION UNDER 37 C.F.R. 1.132 Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 | Attorney Docket No. | CALD-007 |
| | First Named Inventor | Caldwell, Larry |
| | Confirmation Number | 3764 |
| | Application Number | 10/029,407 |
| | Filing Date | December 26, 2001 |
| | Group Art Unit | 1615 |
| | Examiner Name | Ghali, Isis D. |
| | Title: | Methods and compositions for treating headache pain with topical NSAID compositions |

Dear Sir:

I, Bradley Galer, am an inventor of the subject matter claimed in the patent application identified above. A copy of my C.V. which demonstrates that I am qualified to speak on the level of one of skill in the art is already of record in this application.

I hereby declare as follows:

1. I have read the Office Action dated March 30, 2006 that issued in the above referenced case. I have also read Van Engelen (U.S. Patent No. 6,416,772), the reference cited in support of the rejections made by the Office.

2. Van Engelen characterizes the topical analgesic solution disclosed therein as follows:

solution is effective for the relief of aches and pains associated with, among other things, muscular aches, strains and cramps, arthritis, joint pain, burns, lower back discomfort, bursitis, rheumatism, insect bites, and sports injuries, athlete's foot, shingles, headaches, menstrual cramps, and tennis elbow.

See column 3, lines 56 to 62.

3. As can be seen with reference to the above, Van Engelen teaches that the analgesic solution disclosed is effective for relieving the aches and pains of muscles, joints, cramps, headaches and the like. As such, the pain conditions which Van Engelen targets are conditions arising from peripherally induced musculoskeletal mechanisms or peripheral nerve damage (shingles), and not headaches arising from central nervous system mechanisms, such as migraine, cluster, tension headaches, or indomethacin responsive headaches. This can clearly be seen with reference to the working example set forth in Van Engelen, wherein the headache to be treated was simply associated with head pains and not associated with nausea, vomiting, light/sound sensitivities, and/or eye symptoms that are commonly associated with headache conditions that are caused by an underlying disturbance in the central nervous system.

4. In contrast, headaches such as migraine, cluster, tension headaches, and indomethacin responsive headaches (IRH) are not caused by musculoskeletal or peripheral nerve damage mechanisms, rather they are headaches that are caused by disturbances in the central nervous system. See e.g., Exhibit A, Aurora, "Pathophysiology of Migraine Headache" and Dodick, "Indomethacin-responsive Headache Syndromes." Accordingly, migraine, cluster, tension headache, and IRH conditions are considered unique clinical entities distinct from those conditions of headache pains caused by localized musculoskeletal mechanisms (e.g., muscle contractions). In fact, the International Association for the Study of Pain, the world's foremost medical and scientific pain society characterizes migraine headaches as arising from central nervous system mechanisms, and not the musculoskeletal system. See Exhibit B, Page 77.

5. Therefore, one of skill in the art would understand Van Engelen to be directed solely to the treatment of headaches caused by musculoskeletal disorders and that musculoskeletal disorders do not include headaches arising from central nervous system mechanisms (e.g., headaches such as migraine, cluster, tension headaches, or indomethacin responsive headaches). One of skill in the art would understand that musculoskeletal disorders do not include migraine, cluster, tension headaches or IRH because such headaches arise from a completely different system and are categorized differently by the International Headache Society, IHS, the foremost international headache medical and research group, as well, as evidenced by Exhibit C (<http://www.i-h-s.org/>).

6. As such, Van Engelen does not teach one of skill in the art anything about the treatment of headache conditions arising from central nervous system mechanisms, such as migraine, cluster, tension headaches and/or IRH.

7. Accordingly, one of skill in the art would not have a reasonable expectation of success based on Van Engelen in treating headaches with topical NSAID formulations.

I hereby declare that all statements made herein are of my own knowledge and are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued there from.

Respectfully submitted,

Date: 02 JUNE 2006

By: 

Bradley Galer

enc:

- Exhibit A- Aurora, "Pathophysiology of Migraine Headache," and Dodick, "Indomethacin-responsive Headache Syndromes."
- Exhibit B- Classification of Chronic Pain, page 77
- Exhibit C (<http://www.i-h-s.org/>)